510(k) Summary
IRIS™ Anterior Cervical Plate System

APR 2 9 2013

Submitted By:

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510(k) Contact:

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Date Prepared: January 25th, 2013

Trade Name: IRIS™ Anterior Cervical Plate

Common Name: Spinal Fixation System

Classification: KWQ, CFR 888.3060, Class II

Predicate Device: Life Spine Anterior Cervical Plate System (K070285)
K2M Cervical Plate System (K113329)

Device Description:

The IRIS™ Anterior Cervical Plating System consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Fixation is provided by bone screws inserted through the plates and into the vertebral body of the cervical spine using an anterior approach.

The IRIS™ Anterior Cervical Plate System implant components are made from titanium alloy described by ASTM F136 and Nitonol per ASTM F2063. Stainless steel and titanium implant components must not be used together in a construct. LIFE SPINE expressly warrants that these devices are fabricated from the foregoing material specification. No other warranties express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. Do not use any of the IRIS™ Anterior Cervical Plate System components with the components from any other system or manufacturer.

Intended Use of the Device:

Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: (1) Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); (2) Spondylolisthesis; (3) Trauma (including fractures or dislocations); (4) Spinal cord stenosis; (5) Deformity or curvatures (i.e. kyphosis, lordosis or scoliosis); (6) Tumors; (7) Pseudarthrosis; (8) Failed previous fusions.

Nota Bene: This device system is intended for anterior cervical interverterbral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Technological Characteristics:

The IRIS™ Anterior Cervical Plate System is substantially equivalent to the predicate system in terms of design, materials, indications for use and sizing.

Material:

The IRIS™ Anterior Cervical Plate System material is 6AL-4V-ELI titanium manufactured according to ASTM F136 and Nitonol manufactured according to ASTM F2063. The device is comprised of a variety of non-sterile, single use components.

Performance Data:

Static compression, static torsion and dynamic compression testing per ASTM F1717 as well as Screw Push-out testing were presented to demonstrate the substantial equivalency of the IRIS™ Anterior Cervical Plate System.

Conclusion:

The information presented demonstrates the substantial equivalency of the IRIS™ Anterior Cervical Plate System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

Life Spine, Incorporated
% Mr. Randy Lewis
Director, RA/QA
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K130202
Trade/Device Name: IRIS™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 27, 2013
Received: February 28, 2013

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): _____

Device Name: IRIS™ Anterior Cervical Plate System

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Nota Bene: This device system is intended for anterior cervical interverterbral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use _x_ (Part 21 CFR 801 Subpart D)	And/Or	Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices